

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JEFFREY W. MOEHLENBRUCK
JOHN P. RANIERI

Serial No.: 10/812,268

Filed: March 29, 2004

For: METHODS AND COMPOSITIONS FOR
TREATING INTERVERTEBRAL DISC
DEGENERATION

Confirmation No.: 2977

Group Art Unit: 1656

Examiner: Marsha M. Tsay

Attorney Docket: 2103.013882/KDG
(SBI-064-DIV)

CUSTOMER NO. 45488

**DECLARATION OF JEFFREY W. MOEHLENBRUCK AND JOHN P. RANIERI
UNDER 37 C.F.R. 1.131**

We, Jeffrey W. Moehlenbruck and John P. Ranieri, state as follows:

1. We are the inventors of the above-identified patent application.
2. Exhibit 1 (attached hereto) is a document relating to the preparation of cross-linked nucleus pulposus tissue for use in a method of manufacturing an intervertebral disc implant. Exhibit 2 (attached hereto) is a document relating to the implantation of an intervertebral disc implant prepared according to Exhibit 1. Both Exhibits were prepared before August 13, 1999, and describe work done before that date.
3. We were employees of Sulzer Innotec, Ltd., or its corporate successors as of the date of the documents presented in Exhibits 1 and 2. The work described in the Exhibits was performed under our direction.

4. Exhibit 1 shows that nucleus pulposus tissue was extracted from a donor (specifically, pig) and at least a portion of it was cross-linked (specifically, by photo-fixation) in a method of manufacturing an intervertebral disc implant (specifically, an animal implant for at least one sheep).
5. Exhibit 1 also shows that the cross-linked nucleus pulposus material was further combined with an intervertebral disc regenerating material (specifically, BP, which is a combination of growth factors extracted from bovine bone according to Poser *et al.*, U.S. Pat. No. 5,290,763).
6. Exhibit 2 shows that an intervertebral disc implant (referred to as "PF Matrix/BP") was implanted intervertebrally (specifically, in at least one sheep).
7. As demonstrated by the results shown in Exhibits 1 and 2, we performed a method of manufacturing an intervertebral disc implant comprising obtaining donor nucleus pulposus tissue and cross linking at least a portion of the nucleus pulposus tissue prior to August 13, 1999. Prior to that date, we also performed a method as stated above and further comprising combining the nucleus pulposus tissue with an intervertebral disc regenerating material.
8. The work described in Exhibits 1 and 2 was performed in the United States of America.
9. We declare that all statements made of our own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001

of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7-2-07


Jeffrey W. Moehlenbruck

Date: _____

John P. Ranieri